

DEPARTMENT OF TRANSPORTATION

[4910-EX-P]

Federal Motor Carrier Safety Administration

[Docket No. FMCSA- 2016-0175]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from eleven individuals for exemptions from the rules prohibiting operation of a commercial motor vehicle (CMV) by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. If granted, the exemptions would enable these individuals to operate CMVs for up to two years in interstate commerce.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA-2016-0175 using any of the following methods:

- <u>Federal eRulemaking Portal</u>: Go to www.regulations.gov. Follow the online instructions for submitting comments.
- <u>Mail</u>: Docket Management Facility; U.S. Department of Transportation, 1200
 New Jersey Avenue, SE, West Building Ground Floor, Room W12-140,
 Washington, DC 20590-0001.

- Hand Delivery or Courier: West Building Ground Floor, Room W12-140, 1200
 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday
 through Friday, except Federal Holidays.
- <u>Fax</u>: 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket ID for this Notice. Note that all comments received will be posted without change to http://www.regulations.gov, including any personal information provided. Please see the Privacy Act heading below for further information.

<u>Docket:</u> For access to the docket to read background documents or comments, go to http://www.regulations.gov, at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to http://www.regulations.gov, as described in the system records notice (DOT/ALL-14 FDMS), which can be reviewed at http://www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE, Room W64-113, Washington, DC 20590-

0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) for a two-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the two-year period. The eleven individuals listed in this notice have requested an exemption from 49 CFR 391.41(b)(4), which applies to drivers who operates CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard found in 49 CFR 391.41(b)(4) states that a person is physically qualified to drive a CMV if that person

Has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive cardiac failure.

In addition to the regulations, FMCSA has published advisory criteria¹ to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section *D. Cardiovascular:* §

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¹ See http://www.ecfr.gov/cgi-bin/text-idx?SID=e47b48a9ea42dd67d999246e23d97970&mc=true&node=pt49.5.391&rgn=div5#ap49.5.391_171. a and https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.

<u>391.41(b)(4)</u>, paragraph 4.] The advisory criteria states that ICDs are disqualifying due to risk of syncope.

Qualifications of Applicants

Charles R. Allen

Mr. Allen is a 47 year old commercial motor vehicle driver in Michigan. A report that he provided from July 2015 from the Veterans Administration Ann Arbor Healthcare System provider indicates, "he has well compensated class-I-II congestive heart failure with and ICD. He has a normal ejection fraction of 50-55%".

William Blake

Mr. Blake is a 57 year old Class A CDL holder in New Hampshire. His ICD was implanted in June 2015 and has never deployed. A January 5, 2016 cardiologist report indicates; "No symptoms referable to ICD or underlying rhythm changes. I believe the risk of recurrent ventricular tachy-arrhythmias or syncope is very low, however, given the history of these abnormalities and the family history of arrhythmias I would favor continued ICD implantation.

Roosevelt Tyrone Brown

Mr. Brown is a 54 year old Class A CDL holder in South Carolina. A March 17, 2016 letter from his cardiologist states that Mr. Brown's ICD was implanted October 15, 2013, and that recent echocardiography demonstrated an ejection fraction in the 25-30 percent range and a calculated ejection fraction of 24% from nuclear stress testing. A March 10, 2016 report from his electrophysiologist indicates that Mr. Brown has reported one shock from his device. Overall he feels well and denies chest pain, shortness of breath, or dyspnea on exertion.

Kevin Coulter

Mr. Coulter is a 60 year old Class A CDL holder in California. A June 2016 letter from his cardiologist states that his ICD was implanted in February 2015. No shock has deployed since implantation. He has been asymptomatic. He has an ejection fraction of 40-45%, most recently measured in April 2015.

John Dudar

Mr. Dudar is a 55 year old Class A CDL holder in Connecticut. An undated cardiologist report indicates that the ICD has been in place since.2003. "He has experienced several shocks from his device and around that time was upgraded to biventricular ICD. At least back to 2009 he has not received any ICD discharges. His device is stable and at this point he really has no significant heart failure symptoms. His last ejection fraction was estimated at 25% in August 2013. His cardiac issues appear stable. He has had no recent ventricular arrhythmias and he has a normally functioning Biy-ICD".

Timothy Godwin

Mr. Godwin is a 51 year old Class A CDL holder in North Carolina. A March 30 2016 report from his cardiac electrophysiologist indicates knowledge of the driver and his condition since 2014 and that (Mr. Godwin) has not required any therapies before or after ICD implant, nor has he lost consciousness at any time. "I consider him to be safer than most other commercial drives who have undiagnosed or untreated cardiovascular problems. I feel that rather than the presence or absence of an ICD in a patient what is most important is the underlying cardiac condition and risk for loss of consciousness. Treated, Mr. Godwin is at average risk".

James Goslee

Mr. Goslee is a 52 year old driver in Maryland. A May 2016 letter from his cardiologist states that his ICD was implanted in June 2104. His ICD has never delivered therapy. He follows up regularly in the office and is free of cardiac complaints. An April 2016 study shows an ejection fraction of 65-70% and an exercise tolerance at 10 minutes of Bruce protocol. The current status of underlying heart condition is low intermediate cardiovascular risk profile.

Richard Hacker

Mr. Hacker is 62 year old Class A CDL holder in Maryland. Medical documents from June 2016 from his cardiologist state that his ICD was implanted in 2007. The device check in June 2016 indicated no events for 10.5 years. Mr. Hacker's ejection fraction is 53%. His medical documentation indicates that he has no symptoms.

Kathryn Kosse

Ms. Kosse is a 63 year old Class D holder in Arizona. A May 2016 letter from her cardiologist states that her defibrillator was implanted in October 2014. "Her ICD has never deployed and her symptoms have completely resolved. Her left ventricular ejection fraction is normal. Ms. Kosse appears to be in stable cardiovascular health".

Joseph Skrzyniarz

Mr. Skrzyniarz is a 56 year old Class A CDL holder in Michigan. He possesses a one-year Michigan waiver dated October 22, 2015 for intrastate driving. A September 15, 2015 cardiologist- electrophysiologist report indicates that his ICD has been implanted since February 2015. He has not received any ICD shocks from his device at this time. "He had two episodes of asymptomatic non-sustained ventricular tachycardia. His

condition is stable over the past year and unchanged. He has not had any ICD shocks or dangerous arrhythmias. He has been asymptomatic and is safe to operate a commercial vehicle in accordance to his job description which was provided. I have no reservations at this time". A September 17 cardiologist report provides that, "To date the device has not been activated and his underlying cardiac condition has been deemed stable."

Wylanne Deon Stafford

Mr. Stafford is a 48 year old driver in Illinois. An April 26, 2016 report from his cardiologist indicates that Mr. Stafford's ICD was implanted in 2011 and has never fired. His cardiologist indicates that since ICD placement, his ejection fraction has normalized to 55% and he is asymptomatic and stable.

II. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

III. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to http://www.regulations.gov and in the search box insert the docket number "FMCSA-2016-0175" and click the search button.

When the new screen appears, click on the blue "Comment Now!" button on the right

hand side of the page. On the new page, enter information required including the specific

section of this document to which each comment applies, and provide a reason for each

suggestion or recommendation. If you submit your comments by mail or hand delivery,

submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying

and electronic filing. If you submit comments by mail and would like to know that they

reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and materials received during the comment

period. FMCSA may issue a final determination any time after the close of the comment

period.

IV. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to

http://www.regulations.gov and in the search box insert the docket number FMCSA-

2016-0175 and click "Search." Next, click "Open Docket Folder" and you will find all

documents and comments related to this notice.

Issued on: July 29, 2016.

Larry W. Minor,

Associate Administrator for Policy.

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